IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

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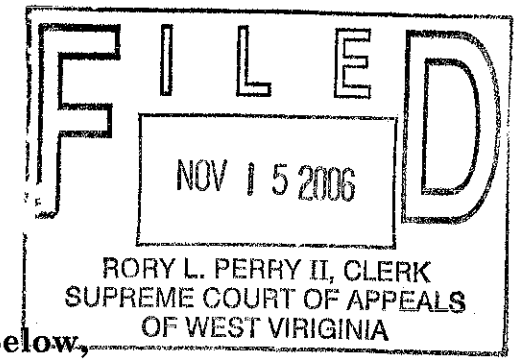
Docket No.: ~~062498~~



JOHNSON & JOHNSON, CORPORATION,
a foreign corporation;

JANSSEN PHARMACEUTICA, INC.,
a foreign corporation and a wholly-owned subsidiary of Johnson & Johnson, Inc.;

Petitioners/Defendants Below,

vs.

THE HONORABLE MARK A. KARL;

ESTATE OF NANCY J. GELLNER,
By Gregory A.Gellner, Executor; and,

DANIEL W. WILSON, M.D.,

Respondents.

RESPONDENT, DANIEL W. WILSON, M.D.'S RESPONSE TO RULE TO SHOW CAUSE IN OPPOSITION TO PETITIONERS JOHNSON & JOHNSON CORP. AND JANNSEN PHARMACEUTICA, INC.'S APPLICATION FOR THE WRIT OF PROHIBITION

COMES NOW the Defendant below/Respondent, Daniel W. Wilson, M.D., by counsel, D.C. Offutt, Jr, Esquire, Stephen S. Burchett, Esquire, Jody M. Offutt, Esquire and the law office of Offutt, Fisher and Nord, pursuant to Rule 14(d) of the West Virginia Rules of Appellate Procedure, and hereby respectfully Responds to the Rule to Show Cause issued by this Court on October 26, 2006, asserting that Petitioner's Application for the extraordinary relief of the Writ of Prohibition is unwarranted and should be denied. In support of this Motion, the Respondent submits the following Memorandum of Law.

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Respectfully Submitted,

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I. KIND OF PROCEEDING AND NATURE OF RULING BELOW

The Defendant below/Respondent, Daniel W. Wilson, M.D., (hereinafter Dr. Wilson), by counsel, D.C. Offutt, Jr, Esquire, Stephen S. Burchett, Esquire, Jody M. Offutt, Esquire and the law firm of Offutt, Fisher and Nord, files this Response to Rule to Show Cause for Petitioner's Application for the Writ of Prohibition pursuant to Rule 14(d) of the West Virginia Rules of Appellate Procedure. Defendants below/Petitioners Johnson and Johnson Corp., and Jannsen Pharmaceutica, Inc., (hereinafter collectively referred to as "Jannsen" or "Petitioner"), filed their application for Writ of Prohibition seeking relief from the Circuit Court of Marshall County's July 13, 2006 Order denying Petitioner Jannsen's "Motion in Limine Regarding Duty to Warn Customers," filed in that court. See "Order," dated June 13, 2006, included in the "Appendix to the Response to Rule to Show Cause in Opposition to Petition for Writ of Prohibition," as **Exhibit A.**

Specifically, the Marshall County Circuit Court held that the West Virginia Supreme Court of Appeals has not recognized the learned intermediary doctrine. The court noted that this doctrine "provides that a prescription drug manufacturer's duty to warn of possible side effects is satisfied if adequate warning is given to a patient's health care provider." See **Exhibit A,** at p. 3. The lower court also noted that this doctrine is an exception to the general rule that a manufacturer's duty to warn of any risks or dangers inherent in the product flows to the ultimate consumer. See id. Instead, the lower court held that "the determination of whether a defendant's efforts to warn of a product's dangers are adequate is a jury question." See **Exhibit A,** at p.

3. (citing Ilosky v. Michelin Tire Corp., 172 W. Va. 435, 307 S.E.2d 603 (1983)). This Court subsequently issued a rule to show cause on September 26, 2006. See "Rule to Show Cause" dated September 26, 2006, included in the "Appendix to the Response to Rule to Show Cause in Opposition to Petition for Writ of Prohibition," as **Exhibit B.**

II. STATEMENT OF FACTS

Dr. Wilson was the primary care physician of Nancy J. Gellner (hereinafter referred to as "Gellner"). On May 19, 1999, Dr. Wilson provided samples of the medication "Propulsid," which he had been given by a sales representative of Jannsen, to Gellner after she complained of, and was diagnosed with, gastroesophageal reflux disease (GERD). Propulsid, the brand name for cisapride, was a prescription drug manufactured by Jannsen Pharmaceutica, Inc., a wholly owned subsidiary of Johnson & Johnson Corp. It is alleged that Propulsid, which was marketed and sold to combat heartburn and acid reflux, proved fatal to hundreds of people due to a side effect associated with the QT interval of the human heart rhythm. In light of the numerous fatalities purportedly attributed to Propulsid, Jannsen decided to simply modify the listed contraindications and box warnings pertaining to Propulsid apparently so not to affect the financial gains brought about by the aggressive marketing campaign it had undertaken to promote this drug. Unfortunately, Nancy J. Gellner died on May 22, 1999, three days after allegedly taking Propulsid. Jannsen was ultimately prompted to discontinue production and sales of Propulsid in 2000.

Gellner's estate instituted suit against Dr. Wilson alleging medical malpractice, and against Jannsen alleging various tort, product liability, and strict liability theories

of recovery. Specifically, Plaintiff has alleged that Propulsid was defective and not reasonably safe, and that the product did not have adequate and effective warnings in light of the dangers associated with its use. See "Complaint," included in the "Appendix to the Response to Rule to Show Cause in Opposition to Petition for Writ of Prohibition," as **Exhibit C**, at ¶¶ 17-19. In fact, the Plaintiff has admitted that the changes and box warnings discussed above were not "effectively communicated by [Jannsen] to prescribing physicians, such as Wilson." See **Exhibit C**, at ¶ 20.

The Plaintiff's expert, Joel Morganroth, who is a cardiologist involved in various drug development studies, has stated that Propulsid was minimally efficacious for its labeled use, and opined that the drug should have been placed on a limited access program to safeguard patients, such as Gellner, when it became clear that Propulsid was associated with serious cardiac risk. See "Propulsid Review Memorandum of Joel Morganroth, M.D.," dated April 29, 2004, included in the "Appendix to the Response to Rule to Show Cause in Opposition to Petition for Writ of Prohibition," as **Exhibit D**, at p. 1. He also believes that the warnings provided by Jannsen in 1998 and 1999 were ineffective or insufficient to adequately warn health care providers, such as Dr. Wilson, of the risk-benefit ratio of Propulsid use. See **Exhibit D**, at p. 1. Furthermore, it has been asserted that Jannsen "knew of increased risks of Propulsid, but that they purposely withheld that information form the FDA and /or delayed conveying the information to the FDA so that the medication could stay on the market longer...." See "Plaintiff's Response Memorandum of Law In Opposition to Johnson & Johnson and Jannsen's Motion for Summary Judgment," dated March 8, 2005, included in the

"Appendix to Response to Rule to Show Cause in Opposition to Petition for Writ of Prohibition," as **Exhibit E**, at p. 4.

In an effort to immunize themselves from any liability for their negligence, Jannsen has petitioned this Court to apply the Learned Intermediary Doctrine to the facts underlying this litigation. For the reasons set forth below, Respondent now submits to the Court that the Learned Intermediary Doctrine has no place in West Virginia jurisprudence, as it disallows the fair apportionment of liability between alleged tortfeasors, circumvents the West Virginia law on informed consent, and does not comport with the present interactions between pharmaceutical companies and patients in our modern medical society. In the alternative, if the Learned Intermediary Doctrine is viable in West Virginia, it is not applicable to the facts of this case as the adequacy of Jannsen's warnings and contraindications are in question. Furthermore, Jannsen engaged in over-promotion and direct-to-consumer advertising, which would act to vitiate any application of the Learned Intermediary Doctrine, even if viable in West Virginia. Lastly, as the Plaintiff in this matter has also alleged a design defect theory of liability against Petitioner Jannsen, the usefulness of the Learned Intermediary Doctrine to the present case would be very limited, even if applicable, as said doctrine applies only to failure to warn claims, and not design defect or manufacturing defect claims. Therefore, even if this Court finds that the Learned Intermediary Doctrine is applicable, and no exceptions to the rule exists in the present litigation, Petitioner Jannsen would by no means be dismissed from this suit.

III. ARGUMENT

A. The Learned Intermediary Doctrine: Introduction and Overview.

Under what is known as the 'Learned Intermediary Doctrine,' a patient's doctor acts as a learned intermediary between the patient/purchaser and the manufacturer, evaluating the patient's needs, accessing the risks and benefits of available drugs, prescribing them, and supervising their use. It is believed that if the doctor is properly warned of the possibility of the side effect in some patients, and is advised of the symptoms normally accompanying the side effect, it is anticipated that injury to the patient will be avoided. See Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974), cert. denied 419 U.S. 1096, 95 S. Ct. 687, 42 L. Ed.2d 688; Kirsch v. Picker International, Inc., 753 F.2d 670 (8th Cir. 1985).

The Learned Intermediary Doctrine arises from the American Law Institute's Restatement (Third) of Torts: Products Liability, which states in pertinent part:

> (d) A prescription drug or other medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
>
> (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
>
> (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Rest. 3d of Torts: Products Liability, § 6 (1998). Comment b to the above cited section of that Restatement states:

> Rationale. The obligation of a manufacturer to warn about the risks attendant to the use of drugs and medical devices that may be sold only pursuant to a health-care provider's prescription traditionally has required warnings directed to health care providers and not to patients. The rationale supporting this "learned intermediary" rule is that only health care professionals are in a position to understand the significance of the risks involved and to access the relative advantages and disadvantages of a given form of prescription-based therapy....

Rest. 3d of Torts: Products Liability, § 6, Comment b (emphasis added). This comment continues by stating that once this warning is given to health care providers, any duty to warn imposed upon a pharmaceutical company to a patient dissolves. Id.

Three different rationales have been articulated to support the Learned Intermediary Doctrine. Primarily, as stated in the above cited comment, it is believed that the prescribing physician is in a superior position to understand and apply the warning, and can "provide an independent medical decision as to whether the use of a drug is appropriate for treatment of a particular patient." See Larkin v. Pfizer, Inc., 153 S.W.3d 758, 763 (2004). Secondly, it is asserted that "manufacturers lack effective means to communicate directly with each patient." Id. at 764. Lastly, proponents of the Learned Intermediary Doctrine assert that "imposing a duty to warn upon the manufacturer would unduly interfere with the physician-patient relationship." Id.

On the strength of the above stated rationale, many courts have adopted the Learned Intermediary Doctrine. Research reveals that the number of states that have adopted the doctrine has been reported as high as 44, however the decision from which such statistic was taken incorrectly claimed that West Virginia was among those 44.

See Vitanza v. Upjohn Co., 257 Conn. 365, 778 A.2d 829, 838 (2001).[1] The American Law Reports article entitled "Construction and Application of Learned-Intermediary Doctrine," which was updated in December of 2005, is submitted as the most accurate compilation of jurisdictions adopting the doctrine. It claims that 30 states, as well as the District of Columbia, have adopted the learned intermediary doctrine when determining the liability of a manufacturer or seller for its alleged failure to adequately warn of the risks associated with its prescription drug. See Diane Schmauder Kane, J.D., Annotation, Construction and Application of the Learned Intermediary Doctrine, 57 A.L.R.5th 1, at § II, 3 (Dec. 2005).

It is, however, conceded that a majority of states have adopted the Learned Intermediary Doctrine, either through the enactment of statutes promoted by the effective lobbying of a state's legislative body through special interest groups, or through judicial fiat. Furthermore, it is also conceded that the federal courts in this jurisdiction believe that this Court would adopt said doctrine if the case presented itself. See, e.g., Rohrbough v. Wyeth Labs., Inc., 719 F. Supp. 470, 478 (N.D. W. Va. 1989); Pumphrey v. C.R. Bard, Inc., 906 F. Supp. 334, 338 (N.D. W. Va. 1995). It must be emphasized, however, that many of the jurisdictions adopting the Learned Intermediary Doctrine did so long ago, and have since created numerous exceptions to the rule itself. Therefore, the question now becomes whether the Learned

[1] Petitioner/Defendant-below Jannsen claims in it's Petition for Writ of Prohibition that this doctrine is nearly universal," and "[c]ourts in all other 48 states which have considered whether to apply the doctrine have accepted it." Research conducted by Respondent and contained in this Response casts doubt upon the accuracy of that assertion.

Intermediary Doctrine remains viable in our modern medical society, and whether such doctrine has a place in West Virginia jurisprudence.

B. A Complete Analysis of the Reasons Purportedly Justifying the Learned Intermediary Doctrine Conclusively Establish that the Doctrine does not Comport with West Virginia's Informed Consent Law or the Provisions of Medical Care in Our Modern Society.

As discussed earlier, courts and commentators have offered that the Learned Intermediary Doctrine is viable because physicians are in a superior position, after evaluating the risks and benefits of treatment, to convey a meaningful, "highly individualized warning" to their patients, as they must do to satisfy their duty to secure informed consent. Odgers v. Ortho Pharmaceutical Corp., 609 F. Supp. 867 (E.D. Mich. 1985) (quoting Rheingold, Products Liability, The Ethical Drug Manufacturer's Liability, 18 Rutgers L. Rev. 947, 987 (1964); Spychala v. G.D. Searle & Co., 705 F. Supp. 1024, 1031-32 (D.N.J. 1988); Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293, 1305 (D. Minn. 1988)). This rationale ignores a physician's duty under state law and the modern procedure in which medications are prescribed by physicians.

Under West Virginia law, as in most jurisdictions, a physician's duty is to advise patients of the material risks of treatment. See Cross v. Trapp, 170 W. Va. 459, 294 S.E.2d 446 (1982) (emphasis added). The physician's actions are analyzed in the context of the information that would be disclosed by a reasonably prudent physician under the same or similar circumstances. A doctor can comply with his or her duty to inform without advising a patient of the possibility of every side effect of a given prescription. See id. However, the result in a jurisdiction shielding a manufacturer

from liability under the Learned Intermediary Doctrine is one of two possibilities. Either a failure to warn claim could remain against a doctor that has fulfilled his or her duty of informed consent, or a patient is left without any available legal remedy, regardless of the extent of injuries, as a result of taking prescription medication. Either outcome cannot be considered a fair and equitable distribution of liability, considering that the primary tortfeasor may very well be the pharmaceutical company claiming immunity via a court's adoption of the Learned Intermediary Doctrine.

Moreover, this rationale also ignores concerns that physicians tend to prescribe drugs with which they are familiar, or for which they have received advertising material, even when studies indicate that better alternatives are available. George W. Conk, Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?, 109 Yale L.J. 1087 (2000). Accordingly, many physicians may not necessarily exercise their independent medical judgment, after considering all alternatives, in prescribing a particular medication for a particular patient. Caroline L. Nadel, The Societal Value of Prescription Drug Advertisements in the New Millenium: Targeted Consumers Become the Learned, 91 J.L. & Pol'y 451, 476 (2001). This result stems from the fact that modern-day physicians operate in an environment where their decisions are affected by the marketing campaigns of pharmaceutical manufacturers, mainly due to frequent visits from sales representatives who provide the physician with numerous office supplies displaying the drug's logo, and deliver the

medication's sales pitch.[2] Even assuming that pharmaceutical manufacturers are not exercising control over physician's judgment through major advertising programs directly focused upon the physician, it must be considered that "patient-choice" as a consequence of direct-to-consumer marketing has acted to significantly diminish the 'independent' exercise of judgment by medical providers. Even though it is the physician that ultimately prescribes a medication, the truth is that, in ever increasing numbers, it is the patients themselves that choose the medications that will ultimately be prescribed for them. This is the very result that pharmaceutical companies hoped to accomplish when engaging in large marketing campaigns. This court may take judicial notice of the fact that the American public is inundated with "direct-to-consumer" advertising which entreats the patients to "ask your doctor" about various prescription medications. One need only turn on the television or pick up a magazine to be exposed to this on a daily basis. Physicians are no longer in that 'superior position' looked upon with great responsibility by the Restatement. Instead this position has been diminished and overcome by pharmaceutical manufacturers through their marketing and advertising programs directed at both physicians and patients alike, and thus have undermined the supporting rationale of the Learned Intermediary Doctrine.

Therefore, because the Learned Intermediary Doctrine cannot equitably coexist with West Virginia's informed consent law, and because direct-to-consumer advertising

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[2] This has been referred to as "over-promotion" on the part of pharmaceutical companies, and discussed below, has been found to be an exception to the Learned Intermediary Doctrine.

has diminished the 'superior position' of a treating physician, no rational reasons exist to allow pharmaceutical companies the large economic benefit they have received through mass marketing without invoking the normal protections associated with our products liability law. Furthermore, the understanding and application of the warning by the treating physician can easily be evaluated by a jury, who may then decide the rightful apportionment of liability between all possible tortfeasors, both physician and pharmaceutical company. As such, no justification exists for dissolving a pharmaceutical company's duty to properly warn a patient/purchaser in today's modern medical society.

Proponents of the Learned Intermediary Doctrine also urge that drug manufacturers lack effective means to communicate directly with patients, making it necessary to rely on physicians to convey the relevant information. In re Certified Questions, 358 N.W.2d 873, 882 (1984) (Boyle J. Dissenting). The money spent on direct-to-consumer advertising, however, has been increasing at an unprecedented rate. In 1997, pharmaceutical companies spent $1.3 billion on such advertisements. The spending grew to almost $1.9 billion in 1998. In the first four months of 2000, pharmaceutical company spending had increased 58% when compared to the first four months of 1999. Nadel, The Societal Value of Prescription Drug Advertisements in the New Millenium, 9 J.L. & Pol'y at 480. In fact, consumer marketing had made the pharmaceutical industry the 13th largest advertiser in the United States. Mitchell S. Berger, A Tale of Six Implants; The Perez v. Wyeht Laboratories Norplant Case and the Applicability of the Learned Intermediary Doctrine to Direct-to-Consumer Drug

Promotion, 55 Food Drug L.J. 525, 562 (2000).

This increase in marketing has also increasingly usurped the physician's position as the patients primary source of information. The drug companies directly target the ultimate consumers via patient brochures, the internet, magazines, newspapers, and television commercials. Not surprisingly, such media focuses upon the benefits of the medication, but will usually contain only a brief mention and/or fine print disclosure of the side effects and contraindications. The obvious reason that drug manufacturers are so adamantly opposed to warning the ultimate consumer about the dangers of their drug or its interactions is their fear that an informed consumer might elect not to use an expensive and profitable drug, and for this reason they claim that no medium exists to effectively communicate with patients. However, when deemed desirable by the pharmaceutical companies to increase overall profits, an adequate means of communication, in fact, seems to exist, as evident from the numerous advertising forums increasingly utilized by these companies.

Lastly, proponents of the Learned Intermediary Doctrine assert that "imposing a duty to warn upon the manufacturer would unduly interfere with the physician-patient relationship." Larkin, 153 S.W.3d at 764. They reason that if warnings contradict the information supplied by the physician, the patient's trust in the physician's judgment will be undermined. In re Certified Questions, 358 N.W.2d at 882. (Boyle, J, dissenting). Other than stating, in general terms, that the physician-patient relationship will be undermined, however, no rational basis has been set forth for concluding that any affect will occur with regard to the physician-patient

relationship.

In reality, the Learned Intermediary Doctrine has no effect on the physician patient relationship, as such a justification ignores the realities of our current health care system. As one commentator noted, the "Norman Rockwell image of the family doctor no longer exists." Lars Noah, Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues, 32 Ga. L. Rev. 141, 180 n.78. (1997). (citing Paul D. Rheingold, The Expanding Liability of the Drug Manufacturer to the Consumer, 40 Food Drug Cosm. L.J. 135, 136 (1985)). Another commentator, indicating that the current health care system may be a death-knell for the Learned Intermediary Doctrine, asserted that the doctrine is a remnant of a dying "golden age" of medicine. Mitchell S. Berger, A Tale of Six Implants: The Perez v. Wyeth Laboratories Norplant Case and the Applicability of the Learned Intermediary Doctrine to Direct-to-Consumer Drug Promotion, 55 Food Drug L. J. 525, 574 (2000).

We live in a day of a billion dollar direct-to-consumer advertising campaign. Pharmaceutical companies engaging in this type of advertising have already encroached upon the physician-patient relationship. By their actions, the pharmaceutical companies have attempted to enlist the consumer as an active participant in health care decisions, rather than as a passive recipient of whatever information a physician deems a material risk of treatment. Indeed, one recent survey indicated that 76% of responding consumers felt that the direct-to-consumer advertisements had assisted them in becoming more involved with their health care decisions. Nadel, The Societal Value of Prescription Drug Advertisements in the New

Millenium, 9 J.L. & Pol'y at 489. Accordingly, "patient-choice is an increasingly important part of our medical legal jurisprudence." Perez v. Wyeth Laboratories Inc., 734 A.2d 1245, 1257 (1999).

For these reasons, rejection of the Learned Intermediary Doctrine would not have a deleterious effect on the physician-patient relationship. To the contrary, its rejection, and concomitant direct warnings to the consumer, would further the goal offered in the Restatement (Third) of Torts, Section 6, comment b, in ensuring that the ultimate consumer was able to make an informed choice as to treatment. See Rest. 3d Torts: Products Liability § 6, comment b (2006). Moreover, as stated above, full disclosure of warnings and contraindications would promote a more meaningful exchange between the patient and physician as a patient may thoughtfully consider the warnings before meeting with their physician; and therefore, carefully deliberate over the consequences. This, in turn, will promote the patient's ability to ask more informed questions. Thus, a complete and thorough analysis of the rationale purportedly justifying the Learned Intermediary Doctrine sufficiently and conclusively establish that said doctrine does not comport with West Virginia's Informed Consent Law or the provisions of medical care in our modern society, and instead disallows the fair apportionment of liability between all possible tortfeasors, and therefore must be rejected.

In further opposition to the application of the doctrine, it must be noted that approximately 2.1 million injuries and approximately 100,000 American deaths a year are attributable to adverse reactions from prescription medication or drug interactions.

See Center for Drug Safety Home Page, at: http://www.centerfordrugsafety.org/pat_newhome.asp (Last visited Sept. 28, 2006). In light of this statistic, the duty to warn should be expansive, not narrowly applied and extended only to physicians. End users of prescription medication cannot be considered incompetent to evaluate the harmful side effects of their prescriptions. Invariably, individuals subjected to life-threatening side effects stand to lose the most, and should not be foreclosed from receiving full disclosure of medical information. These individuals, or their family members, may very well research the warnings and contraindications, and reveal to a physician the additional information needed to save a life. They should not be deprived of this opportunity, simply because the pharmaceutical companies believe them to be too ignorant to comprehend a complex warning.

The current law of all jurisdictions provides that if any other type of product, other than a pharmaceutical product, has caused an injury or death that product's manufacturer would be subjected to liability under general product liability law. See, e.g., Berkebile v. Brantley Helicopter Corp., 337 A.2d 893 (Pa. 1975). This law requires manufacturers to warn consumers of potential dangers associated with the use and/or consumption of their products. The manufacturer is undoubtedly in the best position to provide consumer warnings because it best knows the weaknesses and risks associated with its own products. Further, the manufacturer is most effectively held liable for a failure to warn as doing so promotes efficiency in safety and design procedures. Yet, these general notions of product liability law do not apply to

prescription drugs under a jurisdiction applying the Learned Intermediary Doctrine.

In such a jurisdiciton, a plaintiff is limited to recovering solely from the prescribing doctor, thus limiting not only the injured party's ability for redress, but also allowing a higher percentage of fault to be wrongfully placed upon the local physician who does not possess the thorough knowledge of risks and benefits or cost avoidance that the pharmaceutical company possesses. Stated quite simply, risks normally borne by the manufacturer for injury are largely shifted to the prescribing physician in a jurisdiction applying the Learned Intermediary Doctrine.

As the Supreme Court of New Jersey stated in Perez v. Wyeth Laboratories Inc., 161 N.J. 1, 734 A.2d 1245 (1999):

> Our medical-legal jurisprudence is based on images of health care that no longer exist. At an earlier time, medical advice was received in the doctor's office from a physician who most likely made house calls if needed. The patient usually paid a small sum of money to the doctor. Neighborhood pharmacies compounded prescribed medications. Without being pejorative, it is safe to say that the prevailing attitude of law and medicine was that the "doctor knows best."

Id. at 4, 734 A.2d at 1247 citing Logan v. Greenwich Hosp. Ass'n, 191 Conn. 282, 465 A.2d 294, 299 (1983). However, the court continued by emphasizing:

> For good or ill, that has all changed. Medical services are in large measure provided by managed care organizations. Medicines are purchased in the pharmacy department of supermarkets and paid for by third party providers. Drug manufacturers now directly advertise products to consumers on the radio, television, the Internet, billboards on public transportation, and in magazines.

Id. The New Jersey Supreme Court then asked, "should [the law] follow these changes

in the marketplace or reflect the images of the past?" In answering that question, the court carved out a broad exception to the Learned Intermediary Doctrine, and held that a pharmaceutical manufacturer should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of its products to consumers.[3]

The West Virginia courts have never adopted the Learned Intermediary Doctrine, and therefore are not burdened with the task of carving out large exceptions to the rule that reflect our changing society. The Learned Intermediary Doctrine reduces the sources of recovery for injured patients, promotes the unfair allocation of liability upon local physicians while allowing the pharmaceutical companies that reap

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[3] Shortly after the phrase "Learned Intermediary" was coined, courts began carving out exceptions to the purportedly "universal" acceptance to the doctrine. A cursory analysis of court decisions in which the Learned Intermediary Doctrine has been rejected in the healthcare context demonstrates that the courts have been persuaded by three primary factors: (1) decreased physician involvement; (2) patient choice influences the type of medication; and, (3) increased ability of pharmaceutical manufacturers to reach the general public.

In Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968), the court held that the manufacturer of a polio vaccine had an independent duty to directly the consumer. The court reasoned that in mass immunization clinics such as where the plaintiff received a polio vaccine, a risk existed that "no physician [would be] present to weight the risks and benefits of the drug therapy for each patient." Accordingly, the limited exercise of physician judgment warranted rejection of the doctrine in that context. See also Samuels v. American Cyanamid Co., 495 N.Y.S.2d 1006 (Sup. Ct. 1985) (pharmaceutical company had duty to warn the ultimate consumer if it can be demonstrated that the product is commonly administered without an individualized balancing of the risk to the particular patient).

In addition, courts have rejected the Learned Intermediary Doctrine in the context of oral contraceptives. In Stephens v. G. D. Searle & Co., 602 F. Supp. 379, 381 (E.D. Mich. 1985), the court reasoned that an exception to the Learned Intermediary Doctrine was justified where oral contraceptives were prescribed for continued purposes and the use of contraceptive device was the result of patient choice. Similarly, in MacDonlad v. Ortho PharmaCeutical Corp., 475 N.E.2d 65 (Mass.), cert. denied 474 U.S. 920 (1985), the court reasoned that direct warnings were required with regard to contraceptives because oral contraceptives are drugs that are usually selected by the patient and often not the result of the physician's skilled balancing of benefits and risks. Rather, the prescription is a product of patient choice and "the physician is relegated to a ... passive role." Id. at 69.

the direct beneficial gain to remain immune from their potential negligence, and simply does not properly reflect the modern marketplace. For these reasons, Respondent respectfully requests this Court to declare this antiquated doctrine inapplicable, as it has no place in West Virginia jurisprudence.

C. If The 'Learned Intermediary Doctrine' is Viable in West Virginia, It is Inapplicable to the Present Facts, as the Warnings were Insufficient to Invoke Said Doctrine

(1) Jannsen did not Apprise Dr. Wilson of the Known or Knowable Risks

When applying the Learned Intermediary Doctrine, it is always in the context of a failure-to-warn claim. If the doctrine is applicable, then the question becomes whether the warning provided by the manufacturer or seller was legally adequate to apprise the learned intermediary of the known or knowable risk of harm associated with its product. Diane Schmauder Kane, J.D., Annotation, Construction and Application of the Learned Intermediary Doctrine, 57 A.L.R.5th 1, at § 2a, fn. 12 (Dec. 2005) (citing 28 C.J.S., Drugs and Narcotics § 62) (Dec. 2005). More specifically, it has been held that in order to be adequate, a manufacturer's warning must: (1) indicate the scope of the danger; (2) communicate the extent or seriousness of the potential danger; (3) alert a reasonably prudent practitioner to the danger; and (4) be conveyed in a satisfactory manner. Id. (citing 2 Drug Product Liability § 2); See also 28 C.J.S., Drugs and Narcotics § 62.

In the present case, Plaintiff will offer evidence that Jannsen's warnings and contraindications were inadequate, insufficient, and/or misleading. As stated earlier,

they have retained Dr. Joel Morganroth, M.D. P.C., an expert cardiologist that has been involved in drug development studies. He has opined that (1) the use of Propulsid alone, without contra-indicated medications or pre-existing medical conditions can prolong the QT interval of the human heart rhythm, leading to a possibly fatal form of ventricular arrhythmia; (2) Propulsid was minimally efficacious for its labeled use; (3) Propulsid should have been placed on a limited access program to safeguard patients when it became clear that Propulsid was associated with serious cardiac risk; and, (4) the warnings provided by Jannsen in 1998 and 1999 were ineffective or insufficient to adequately warn prescribers of the risk-benefit ration of Propulsid use. See **Exhibit D**, at p. 1.

These conclusions are based upon significant factual investigation on the part of Dr. Morganroth. Specifically, he has revealed that the FDA sent a formal notice to Jannsen in 1994, stating that it had monitored Jannsen's marketing program and found Jannsen was promoting Propulsid for unapproved doses and that relevant warnings, hazards, contraindications, side effects, and precautions were not included in some of the promotional materials. See **Exhibit D**, at p. 2. Jannsen, however, continued their aggressive marketing campaign of the medication. In 1996, Dr Morganroth states that the FDA denied pediatric approval for children, but despite this fact, the company never communicated this decision to the physicians caring for children and neonatal patients. See **Exhibit D**, at p. 3. The FDA again condemned Jannsen for distributing misleading promotional material that failed to adequately address the safety implications of the use of Propulsid, especially in the area of drug

interactions.

Further, Dr. Morganroth stated in his April 29, 2004 evaluation that:

> By November 1999, the prescribing information for Propulsid on its face mentions risks of serious cardiac arrythmias and sudden death. However, Jannsen's warnings were then couched in language that served to mislead physicians by saying that "Many of these patients also took drugs expected to increase cisapride blood levels..." It then goes on to say "Most patients had disorders that may have predisposed them to arrythmias with cisapride." Rather than simply stating the risk in clear language, they imply safety of the drug as long as the patient does not use contraindicated medications or have a contraindicated condition. However, by this date, Jannsen knew that Propulsid alone could result in death....

See **Exhibit D**, at p. 7.

Dr. Morganroth has also emphasized that, due to the numerous changes in the contraindications and warnings associated with the drug, these warnings were not effectively being communicated to physicians. See **Exhibit D**, at p. 7. In this respect, the Plaintiff alleges that the "Jannsen sales force was constantly over promoting the medication for uses for which it was not approved and minimizing the risks of the medication, so that doctors would continue to sell this very profitable drug." See **Exhibit D**, at p. 5. Plaintiff alleges that Jannsen "provided scripted messages to their sales force to use as a sales pitch indicating that recent FDA demands requiring [Jannsen] to add black box warnings to the Propulsid literature, new drug interaction warnings, new dear doctor letters and labeling changes were all common events for the most widely prescribed drugs so that doctors should continue to prescribe Propulsid as before and not be worried about the drug's safety." See **Exhibit D**, at p. 13.

Plainly, there are facts that indicate Jannsen did not properly warn physicians of the scope of the danger associated with Propulsid use as any communication of this danger was done in a manner that improperly reduced the importance of the danger. Jannsen also failed in their duty to alert practitioners to this danger, as the warning continually changed and was not conveyed in a satisfactory manner. Therefore, as there are facts sufficient for a jury to conclude that the adequacy of the warning failed to legally apprise a learned intermediary of the known or knowable risk of harm associated with its product, the Learned Intermediary Doctrine is inapplicable.

(2) The Adequacy of the Warning is a Question of Fact to be Determined by the Jury, Particularly Where the Warning Was Qualified or Lacked a Sense of Urgency

Many states that apply the learned intermediary doctrine hold that the issue of warning adequacy is a factual question for the trier of fact. In Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 107 Cal. Rptr. 45 (1973), the court held that, although the manufacturer of a broad-spectrum antibiotic included warnings of the danger of blood disease with intermittent or prolonged use of the drug on its labels, the issue of **whether the warnings adequately informed the medical professional of the risks** of blood disease was a **question of fact for the jury**. In doing so, the court noted that the manufacturer aggressively promoted the medication without properly apprising the physicians of the dangers associated with its use. Similar to the case at bar, the court noted that the pharmaceutical company had instructed its salespeople to alleviate the anxiety of physicians concerned about prescribing the drug in order to increase the medications profitability. Id.

Other cases, such as Zanzuri v. G.D. Searle & Co., 748 F. Supp. 1511 (S.D. Fla. 1990), look to the qualifications accompanying the warnings and contraindications. In Zanzuri, the user of an intrauterine device developed pelvic inflammatory disease, and alleged that the manufacturer failed to adequately warn her physician of the risks associated with such use. The court declared that the manufacturer's warning, which stated that "an increased risk of pelvic infection associated with the use of IUD's had been reported," and "while uncomfirmed, this risk appears to be greatest for young women who have never had a baby," was an issue that could only be resolved by a trier of fact, due in part to the qualified language stated above. In the case at bar, similar qualifications, as outlined by Dr. Morganroth and discussed above, accompany the contraindications and warnings associated with Propulsid.

In Williams v. Lederle Laboratories, Div. of American Cyanamid Co., 591 F. Supp. 381 (S.D. Ohio 1984), a tort suit was brought by a woman who alleged that she contracted poliomyelitis as a result of contact with her infant daughter shortly after the child received an oral polio vaccine. In reviewing the adequacy of the vaccine manufacturer's warning that contact with a recent vaccinee might result in paralytic polio, the court stated that such determination was a question of fact to be decided by the trier of fact. In so holding, the court cited the testimony of the Plaintiff's expert, who maintained that the warning was reluctant, equivocal in tone, and lacked a sense of urgency. As Ohio law, which was controlling in Williams, provided that the adequacy of a warning is a question of fact to be determined by a preponderance of the evidence, the warnings of the manufacturer could not be considered on adequacy

grounds as a matter of law. West Virginia law also tenders to the trier of fact the question of warning adequacy in all other failure to warn litigation. See, e.g., Ilosky. Therefore Respondent submits that, if the Learned Intermediary Doctrine is applicable in West Virginia, then the adequacy of a warning still remains a question of fact for the jury.

D. If the 'Learned Intermediary Doctrine is Viable in West Virginia, It is Inapplicable to the Present Facts, as an Exception to Said Doctrine Applies When Pharmaceutical Manufacturers Engage in Over-Promotion

Many courts have held that a warning was inadequate due, in part, to over-promotion of the drug by the pharmaceutical company which acts to nullify the warning given. In many of these cases, the courts have held that the evidence was sufficient to support a finding of liability against the drug company. Janet Fairchild, J.D., Annotation, Liability of Manufacturer or Seller for Injury or Death Allegedly Caused by Failure to Warn Regarding Danger in Use of Vaccine or Prescription Drug, 94 A.L.R.3d 748 at § 2a (Updated Aug. 2002). For example, in Salmon v. Parke, Davis & Co., 520 F.2d 1359 (4th Cir. 1975), the court held that there was sufficient evidence for the jury to conclude that the pharmaceutical company had over-promoted its drug. In that case, the drug Chloromycetin had been prescribed to a patient for the treatment of relatively minor infections after the company revised it's warning. The court states that, although evidence of over-promotion was slight, an advertising calendar which lacked any warning and might remain on a physician's desk as a constant reminder to prescribe the drug could nullify the effect of even a valid warning on the package. Id.

In the case of Love v. Wolfe, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (3rd Dist. 1964), the court held that sufficient evidence was presented to support the jury's conclusion that the drug company's over-promotion invalidated the warning given. The over-promotion at issue in Love took the form of a minimization of the drug's dangers through advertising and statements made by its retail representatives. The court upheld the jury verdict, stating that the company had misled the prescribing physician by aggressive and misleading over-promotion and a failure to warn of the drug's dangers. *Id.*

Further, the court in Incollingo v. Ewing, 444 Pa. 263, 299, 282 A.2d 206 (1971), remarked that a collary to the question of adequacy of warning was whether the company's efforts in promoting the drug had, in fact, nullified the warning given. The court held that the evidence could have been taken to show a failure to warn the medical profession because of over-promotion. The court also noted that, if the drug company was on notice that the antibiotic was being used indiscriminately and thereafter failed to try to restrict its use to proper situations then it could be found negligent on this basis as well.

In the case at bar, the record is replete with evidence that Jannsen knew of the increased risks associated with Propulsid, however withheld and delayed disclosure of this information while Vice President of Sales Steve Zollo directed his sales representatives to "continue to sell the hell out of Propulsid." See "Propulsid Link Official Sales Team Newsletter," dated May 1999, included in the "Appendix to the Response To Rule to Show Cause in Opposition of Petition for Writ of Prohibition," as

Exhibit F. This statement was made at a time when Jannsen was well aware that Propulsid was continually being incorrectly prescribed to between 38% and 68% of patient/purchasers which confirms that their labeling was ineffective. See "Email Sequence from Jan Gheuens, Jannsen Employee," dated December 15, 1998, included in the "Appendix to the Response to Rule to Show Cause in Opposition of Petition for Writ of Prohibition," as **Exhibit G**. Evidence exists that Jannsen engaged in over-promotion of Propulsid while knowing that the medication was potentially being incorrectly prescribed, and therefore a jury could certainly find that any warning was effectively nullified by their actions. Consequently, the Learned Intermediary Doctrine, if viable in the state of West Virginia, would not be applicable.

E. If the 'Learned Intermediary Doctrine is Viable in West Virginia, It is Inapplicable to the Present Facts, as an Exception to Said Doctrine Applies When Pharmaceutical Manufacturers Engage in Direct-to-Customer Advertising.

Recall that the Learned Intermediary Doctrine arises from the American Law Institute's Restatement 3d of Torts: Products Liability § 6:

> (d) A prescription drug or other medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
>
> (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
>
> (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

At this time, attention is directed to subsection (d)(2), immediately above. In this section, the Restatement emphasizes that reasonable instructions or warnings must be provided to the patient in certain circumstances, even when applying the Learned Intermediary Doctrine. Comment e in this regard allows for possible exceptions to the Learned Intermediary Doctrine to become applicable under subsection (d)(2) through "developing case law." See Rest.3d of Torts: Products Liability § 6, comment e (2006). Comment e continues by stating that "Several decisions indicate that consumer-directed advertising is a factor to be taken into account in deciding whether to apply the learned intermediary rule" Id. citing Stephens v. G.D. Sealre & Co., 602 F. Supp. 379 (E.D. Mich. 1979); Hill v. Searle Labs., 884 F.2d 1064 (8th Cir. 1989).

Respondent now submits that, even if the Learned Intermediary Doctrine is viable in the state of West Virginia, this Court should declare direct-to-consumer advertising as a circumstance that requires the duty to warn be extended to the patient/purchaser. It is simply unfair and inequitable to allow pharmaceutical companies to advertise directly to the consumer, portraying the strengths and attributes of their medicine in their most favorable light, and then shield them from liability for the drugs weaknesses and dangers. When pharmaceutical companies engage in aggressive direct marketing campaigns to promote a prescription drug, they pierce the shield of the learned intermediary doctrine.

To support this proposition's application in the present case, the Plaintiff contends that evidence at trial will show Jannsen aggressivly marketed Propulsid directly to consumers. See **Exhibit E**, at 12. They also have declared to offer evidence

that "Propulsid was the sixth most advertised prescription drug." See id. Therefore, in light of these facts, compounded with the knowledge that Jannsen continued their aggressive marketing campaign while it was aware that the drug was potentially being incorrectly prescribed, the Respondent now submits to this Court that, even if viable, the Learned Intermediary Doctrine is inapplicable to the present case. As the New Jersey Supreme Court in Perez stated, "when mass marketing of prescription drugs seeks to influence a patient's choice of a drug, a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its products should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product." Perez, at 5, 734 A.2d at 1247.

F. A Writ of Prohibition is Not the Appropriate Remedy

Lastly, it is a familiar and well-rehearsed subject of West Virginia jurisprudence that "prohibition lies only to restrain inferior courts from proceedings in causes over which they have no jurisdiction[,] [or, where] they are exceeding their legitimate powers, and may not be used as a substitute for a petition for appeal or certiorari." Hoover v. Berger, 199 W. Va. 12, 20-21, 483 S.E.2d 12, 20-21 (1996) (citing Syl. Pt. 1, Crawford v. Taylor, 138 W. Va. 207, 75 S.E.2d 370 (1953)). When "determining whether to entertain and issue the writ of prohibition for cases... where it is claimed that the lower tribunal exceeded its legitimate powers," this Court will undertake the examination of the following five factors:

> (1) Whether the party seeking the writ has no other adequate means, such as direct appeal, to obtain the desired relief;

(2) Whether the petitioner will de damaged or prejudiced in a way that is not correctable on appeal;

(3) Whether the lower tribunal's order is clearly erroneous as a matter of law;

(4) Whether the lower tribunal's order is an oft repeated error or manifests persistent disregard for either procedural or substantive law; and

(5) Whether the lower tribunal's order raises new and important problems or issues of law of first impression.

Id. at Syl. Pt. 4.

This Court "will use prohibition in this discretionary way to correct only substantial, clear-cut, legal errors plainly in contravention of a clear statutory, constitutional, or common law mandate which may be resolved independently of any disputed facts and only in cases where there is a high probability that the trial will be completely reversed if the error is not corrected in advance." Hinkle v. Black, 164 W. Va. 112, 121, 262 S.E. 2d 744, 749-50 (1979) (emphasis added). Furthermore, "[w]rits of prohibition provide a drastic remedy to be invoked only in extraordinary situations." State ex rel. Thrasher Eng'g, Inc. v. Fox, 624 S.E.2d 481 citing State ex rel. Allen v. Beddell, 193 W. Va. 32, 37, 454 S.E.2d 77, 82 (1994).

First, the present litigation does not meet the above stated criteria. Plaintiff has alleged not only failure to warn, but also design defect as well as strict liability and simple negligence theories of recovery. In that respect, it must be noted that any possible application of the Learned Intermediary Doctrine would be applicable simply to Plaintiff's failure to warn claim, and then only to the extent that the jury could in

some unforeseeable fashion determine that the warnings were adequate. It would under no circumstance affect any of Plaintiff's other theories of recovery. Respondent assumes that Petitioner has undertaken this exercise to gain the advantage of a favorable jury instruction in regards to its duty to warn. As such, the outcome of a trial would not be completely reversed, even if this issue was properly brought on appeal.

Secondly, the Petitioner asks this Court for relief through the extraordinary Writ for what they believe to be a clear error of law. The Respondent can't help but wonder that, for such a clear error of law, why did the Petitioner believe it necessary to include 12 pages of facts in their 22 page application. The answer may very well be that this case hinges upon disputed facts concerning the warnings and contraindications associated with Propulsid which would directly affect any possible application of the Learned Intermediary Doctrine; therefore making the application for the Writ improper. In light of the issues and present facts, the Respondent submits that Petitioner's Application for the Writ has improperly been brought before this Court and should therefore be denied on procedural grounds.

IV. CONCLUSION

In an effort to minimize liability for their potential negligence, Jannsen has petitioned this Court to apply the Learned Intermediary Doctrine to the facts underlying this litigation. It must be emphasized that the practical effect of the Learned Intermediary Doctrine is to dissolve a pharmaceutical company's duty to warn

its purchasers of the dangers associated with its product. In this respect, the Respondent respectfully urges this Court not to adopt such a stance for the State of West Virginia.

For the numerous and varied reasons set forth above, Respondent submits that the Learned Intermediary Doctrine has no place in West Virginia jurisprudence, as it disallows the fair apportionment of liability between alleged tortfeasors, circumvents the West Virginia law on informed consent, and does not comport with the present interactions between pharmaceutical companies and patients in our modern medical society. In the alternative, if the Learned Intermediary Doctrine is viable in West Virginia, it is not applicable to the facts of this case, as the adequacy of Jannsen's warnings and contraindications are in question. Furthermore, Jannsen engaged in over-promotion and direct-to-consumer advertising, which would at to vitiate any application of the learned intermediary doctrine, even if viable in West Virginia. Lastly, as the Plaintiff in this matter has also alleged a design defect theory of liability against Petitioner Jannsen, the usefulness of the learned intermediary doctrine to the present case would be very limited, even if applicable, and by no means would dismiss Jannsen from the present litigation.

WHEREFORE, for the foregoing reasons, the Defendant, Daniel W. Wilson, M.D., by counsel, hereby respectfully requests that this Honorable Court deny Petitioner's Application for Writ of Prohibition, and for such other relief as this Honorable Court deems just.

DANIEL W. WILSON, M.D.

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IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

Docket No.: 062498

JOHNSON & JOHNSON, CORPORATION,
a foreign corporation;

JANSSEN PHARMACEUTICA, INC.,
a foreign corporation and a wholly-owned
subsidiary of Johnson & Johnson, Inc.;

Petitioners/Defendants Below,

vs.

THE HONORABLE MARK A. KARL;

ESTATE OF NANCY J. GELLNER,
By Gregory A.Gellner, Executor; and,

DANIEL W. WILSON, M.D.,

Respondents.

CERTIFICATE OF SERVICE

I, Stephen S. Burchett, counsel for the defendant, Daniel W. Wilson, M.D., do hereby state that the foregoing "**Response to Rule to Show Cause in Opposition to Petitioners Johnson & Johnson Corp., and Jannsen Pharmaceutica, Inc.'s Application for Writ of Prohibition and Supporting Memorandum of Law**" was served upon counsel of record, via U.S. Mail, postage prepaid, this 15 day of November, 2006:

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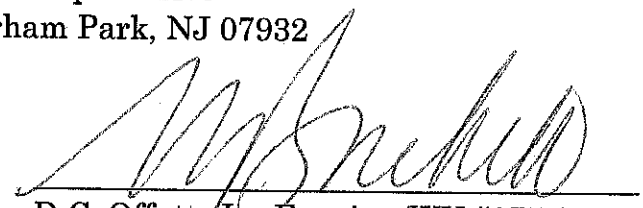

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